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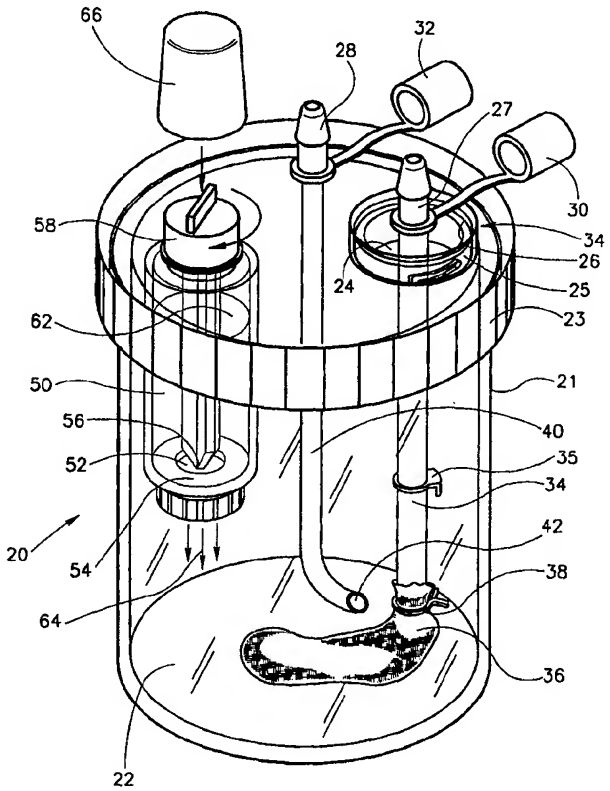
(54) Title: SUCTION–BASED TISSUE COLLECTING DEVICE

(57) Abstract

A suction drainage device for use in vacuum aspiration procedures is provided. The device has a tissue collecting container with an inlet port for connecting to an inlet tube line leading from the source to be drained, and a vacuum port for connecting to a vacuum source. It comprises an inlet duct which extends within the container from the inlet port terminating at an end fitted with a tissue trap for retaining tissue bits and allowing fluid passage therethrough; a vacuum duct which extends within the container from the bottom wall of the container to the vacuum port; and a sealed reservoir integral within the container and containing a liquid tissue treatment material and provided with an external actuator for dispensing of the liquid tissue treatment material into the container so as to flood the tissue bits with said liquid.



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SUCTION-BASED TISSUE COLLECTING DEVICE

FIELD OF THE INVENTION

The present invention relates to a suction drainage device for use in vacuum aspiration procedure in which tissue or body fluids are removed from the body. Particularly, the invention relates to such a device for use in a variety of medical procedures where body fluid and tissue are sucked together and where it is desired to separate between the tissue and the fluid, e.g. for subsequent pathological examination of the collected tissue or cytological assay of cells in the fluid. A particular example for use of such a system is in dilatation and curettage (D&C procedure).

BACKGROUND OF THE INVENTION

In various medical procedures a tissue or body fluid is removed from the body by vacuum aspiration. A specific example is a D&C procedure where the lining of the uterus is scraped to remove embryonic tissue in order to terminate an undesired pregnancy, to remove tumorous and pre-tumorous tissue, etc. It is usually desired to subject the tissue collected in such a procedure to a pathological examination, e.g. to determine the existence of a cancerous or a pre-cancerous state. As tissue is typically sucked together with body fluids including blood, mucous, etc., in order to examine the tissue, it has to be separated from the fluid. Furthermore, it is at times desired to perform a cytological examination on cells in the sucked body fluids.

Another problem of such aspiration procedures is that the collected biological material may often be highly infectious and there is a need to protect medical personnel from direct contact with this potentially hazardous material. Also the material which is used to treat the tissue or cells for fixation or preservation (all such material to be referred to herein as *"treatment material"*) may also be hazardous and direct contact therewith should also be avoided.

U.S. Patents 5,185,007, 5,234,419 and 5,589,145, disclose a suction drainage device that reduces the exposure of the medical personnel to potentially infectious waste material. The device has a collecting chamber which is associated with a reservoir containing waste treatment material, which can be opened by the user to allow release of the waste treatment material into the chamber. U.S. Patent No. 5,549,585, discloses a suction drainage device with a receptacle which cooperates with an external container, holding a waste treatment material, e.g. a gelling agent, which once fitted with the receptacle can release the waste treatment material therein. U.S. Patent No. 5,757,293 discloses a suction drainage system where the inlet suction tube is fitted with a tissue collector, typically a nylon mesh, for collecting the tissue bits. The tissue collector with the collected tissue bits can then be removed for tissue staging for pathological examination.

GENERAL DESCRIPTION OF THE INVENTION

It is an object of the invention to provide a device for use in vacuum aspiration procedures (a suction drainage device) which provides a new solution to both the medical personnel performing the aspiration procedure as well as to the medical personnel performing a subsequent examination of the collected biological material (tissue bits, body fluids, cellular material in the body fluids, etc.).

It is particularly an object of the invention to provide a suction drainage device which protects the medical personnel from direct contact with

the aspirated biological material during the procedure and at the same time allows easy separation between collected tissue bits and fluid.

It is another object of the invention to provide a suction drainage device which protects the medical personnel from direct contact with the potentially hazardous treatment material.

It is an object of the invention to provide a novel, typically designed single use suction drainage device for collecting tissue bits, separating between them and the fluid, and treating the collected tissue bits with a treatment material, without any substantial risk of contamination of the personnel by either the collected tissue or fluid, or the treatment material.

It is an object according to one preferred embodiment, to provide a system for the separation and separate containment of aspirated tissue bits on the one hand and body fluids and cellular material suspended therein on the other hand for subsequent separate examination.

The present invention provides a device and system, simple and convenient for use, which provides an overall solution for aspirating, collecting and subsequent examining of tissue bits, body fluids and cellular material contained in the body fluids, without exposure of the medical personnel to either the collected material or to the treatment material. The device in accordance with the invention is particularly useful as a disposable, single-use device, although in some embodiments, the device may also be made to be reusable.

The present invention provides a suction drainage device comprising a tissue collecting container with an inlet port for connecting to an inlet tube line leading from the source to be drained, and a vacuum port for connecting to a vacuum source; the device being characterized by:

an inlet duct which extends within the container from the inlet port and terminating at an end fitted with a tissue trap for retaining tissue bits and allowing fluid passage therethrough;

a vacuum duct which extends within the container from the bottom wall of the container to the vacuum port; and

a sealed reservoir integral within the container and containing a liquid tissue-treatment material and provided with an external actuator for dispensing of the liquid tissue treatment material into the container so as to flood the tissue bits with said liquid.

The vacuum duct in the device of the invention allows to drain liquids out of the container. At times it is also desired to retain collected liquids within the container, e.g. in case the drainage system does not have a separate liquid trap. Thus, by one embodiment, the container comprises a second vacuum port, devoid of vacuum duct; the user can then connect the vacuum tube to either one of the two vacuum ports, depending on the system's set up. In addition, a device in accordance with this embodiment having two vacuum ports, one provided with the vacuum duct and the other without, can serve as a standard design for a device in a system comprising two such devices, where one for collection of tissue bits and the other serving as a liquid trap (in this connection see also below). For ease of description, a device of the invention according to this embodiment having two vacuum ports, will be referred to herein as the *"two vacuum port device"*).

The second vacuum port, that devoid of a vacuum duct, may typically be fitted with a unit designed to prevent withdrawal of liquid out through the vacuum port. Such unit may, for example, be a float valve as known *per se*. In addition, the second vacuum port may also be provided with a biological filter, which is also known *per se*.

The device of the invention may be used in a variety of vacuum aspiration procedures, a particular example being the DNC procedure materially used to terminate undesired pregnancy primarily in the first trimester of pregnancy.

The device of the invention is typically a disposable device, designed for a single use. The device may be provided together in a

ready-to-use configuration or may provide a collection of components for assembling the device. In addition, the device may also at times be provided with a probe for tissue of fluid collection (or both) already connected to the inlet port.

The tissue trap may be rigid or flexible, slotted and/or perforated, and constructed of metallic, synthetic, cloth, and other types of materials, depending on the requirements and the preference of a particular user. An important requirement of the structure and construction of the trap is that it allows, on the one hand, liquid drainage therethrough, and on the other hand, has pores of a mesh size such that tissue bits are retained within it. In accordance with one embodiment, the trap is a small container with one or more walls which are either perforated or fitted with a sieve. According to another embodiment, the trap is a flexible or pliable net, typically made of a nylon mesh.

The vacuum duct which extends to the bottom has an opening which is designed in a manner allowing an almost complete removal of all fluids drained through the tissue trap.

The reservoir may have various designs permitting it to be sealed in a storage state, while allowing opening and dispensing of the treatment material into the container when in use. By one embodiment, the reservoir has an opening fitted with a closure member which can be displaced from a storage to a dispensing position to open the opening once actuated by the user. By another embodiment, the opening of the reservoir it fitted with a tearable or pierceable wall portion, e.g. a film which is ruptured upon user actuation. The amount of liquid treatment material contained within the reservoir should preferably be sufficient so once dispensed into the container it at least floods all the tissue bits contained in the tissue trap. Typically, the tissue trap will be at the bottom of the container so as to minimize the amount of liquid treatment material required to flood the tissue bits.

In accordance with an embodiment of the invention, the tissue collection device is connected in a series to a liquid trap for collecting liquid drained from the container. The liquid trap may be a device (*"the second device"*) similar to the tissue collection device (*"the first device"*), having an inlet port and a vacuum port, with the inlet port being connected to the vacuum port of the first device and its outlet port being connected to a vacuum source. In distinction to the first device, in the second device there is no duct extending from the vacuum port to the bottom wall of the container, whereby fluid, which enters the second device is collected at its bottom. In accordance with a preferred embodiment, the second device also comprises an integral reservoir which may have the same or a different design than the reservoir of the first device, and which also contains a treatment material, for treating the collected liquid.

By one embodiment of the invention, both the first device and the second device are a standard two vacuum port device, with a different vacuum port being used in each of the devices, while the other port being sealed. Notwithstanding their potential identity in design, the reservoirs in the two devices may contain different treatment material, for example, a fixative for fixing the collected tissue bits in the first device and a preservation medium for maintaining the chemical integrity of the collected fluids or preserving cellular material in the collected fluid in the second device.

The treatment material in the reservoir of the first or the second container may be selected based on need, and may be any one or such materials known *per se*. In accordance with one embodiment, the treatment material in the reservoir of the first container is a fixative to fix the tissue for subsequent staging for pathological examination. In accordance with another embodiment, the treatment material in the reservoir of the second container is a preservation medium to preserve the cellular material contained in the collected liquid.

In order to allow subsequent examination of collected biological material (tissue bits in the first container and body fluid or cellular material

suspended therein in the second container) the container should be fitted with an arrangement to either access the collected material or to remove it from the container. Such a closure may for example be a lid sealing the container during use and transportation but which can be opened to assess the collected biological material. In addition, the container, rather than having a lid, may be provided with a small opening, fitted with a closure which can be removed to allow access to the collected material or their removal. By one specific example, the vacuum port with its associated duct is formed within such a closure, which once opened can be removed with the trap containing the tissue bits, connected thereto. A device of the invention may also be provided with an integral aspiration system to aspirate the collected fluid system from within the container.

The invention will now be illustrated in some non-limiting specific embodiments, shown in the annexed drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is an isometric view of a suction drainage device according to an embodiment of the invention, with walls made transparent to show internal elements.

Fig. 2 shows a system with two devices connected in series, with one being a tissue collection device, and another serving as a liquid trap.

Fig. 3 shows the system of Fig. 2 during suction.

Fig. 4 shows the system of Fig. 2 after ceasing the suction operating and releasing the treated material into each of the containers.

Fig. 5 shows a device in accordance with another embodiment of the invention.

Fig. 6 shows the device of Fig. 1, after treatment with a treatment material, at a draining stage for draining of the tissue trap prior to removal thereof for pathological examination.

DESCRIPTION OF SPECIFIC EMBODIMENTS

Reference is first being made to Fig. 1 showing a device **20,** for use in a suction drainage system for the collection of tissue bits. The device has container **21** with a generally cylindrical shape, having a bottom wall **22.** As will be appreciated, the container may have a variety of other shapes and a cylindrical shape is a mere non-limiting example. The walls of the container shown herein are transparent, although this is a mere example and one can appreciate that this need not necessarily be so. The container is typically made of a plastic material, although it may be made of any other suitable material, such as glass, metal, etc. The container is perfectly made to be disposable, intended for a single use.

The device **20** has a lid **23**, which in the specific example is screw-fitted in a sealing manner, at a top opening of the container. The sealing may obviously be by a variety of other means known *per se,* particularly where the container is not cylindrical. The container of this embodiment is provided with an additional opening **24,** defined by upright cylindrical wall **25,** sealed in a bionet-type fitting by plug member **26**. Defined within plug member **26** is an inlet port **27**, having a ribbed end for a fluid tight connection with a flexible inlet tube line (not shown), as know *per se*. Defined in lid **23** is a vacuum port **28**, for connection to a vacuum source (not shown). Each of ports **27** and **28** is associated with a respective cover, **30** and **32** for sealing these ports.

Extending downward from inlet port **27** is an inlet duct **34,** provided with a hook member **35** and fitted at its lower end, with a trap **36,** for trapping tissue bits. The trap may be made of a wide variety of material, such as nylon mesh, with pore sizes, typically not exceeding ___ μm. Trap **36** attached to the end of duct **34,** e.g. by means of spring ring **38,** or by any other suitable means.

As will be appreciated, and as will also be illustrated with respect to the embodiments of Figs. 5 and 6, once plug member **26** is opened and

removed, it removes with it duct **34** with its attached trap **36**. Hook member **35** may then be hung on to cylindrical wall **25** to allow drainage of trap **36**.

Extending downward from vacuum port **28**, is a vacuum duct **40**, terminating, at a bottom wall **22**, in a drainage opening **42**, situated at the end of a short horizontal section of duct **40**.

The device **20** further has a reservoir **50**, depending downward into the container from lid **24**. The reservoir **50** has a pierceable closure film **52**, fitted on an opening of bottom wall **54**. Situated inside the reservoir **50**, is a pointed spike **56**, vertically displaceable by user manipulation, which in this specific embodiment is achieved by clockwise turning of manipulating knob **58**; as a result of such displacement, the spike pierces film **52**, allowing dispensing of the content of the reservoir into the container.

The reservoir **50**, which, for reasons of illustration, is seen with transparent walls (which may either be transparent or not transparent), contains a liquid treatment material **62**, typically a tissue fixative. A specific example of a fixative is formaldehyde.

The amount of treatment material **62** contained within reservoir **50**, is such so that once released into the container, as represented by arrows **64**, it floods the bottom of the container, such as to entirely cover trap **36**, as will be illustrated also further below (see Fig. 3).

The vertical displacement of spike **56** is the result of a hellical displacement of manipulating knob **58**. In order to avoid accidental displacement prior to use, knob **58** is provided with a tempering proof cap **66**.

Fig. **2** shows a suction drainage system, comprising two devices: a first device **20**, identical to that shown in **Fig. 1**, and a second device **80**. Device **80** is similar by many of its components to device **20**, and like components are given like numbers with a prime indication. The two containers are connected by a tube **81** leading from port **28** of device 20 to port **27'** of device **80**. Port **27** of device **80** is seen connected to an inlet tube **82** and port **28'** of device **80** is connected to a vacuum tube **83**.

One important difference between device **80** and device **20** is that device **80** does not have a vacuum duct, such as duct **40** of the first device **20**. Furthermore, in the shown embodiment, the inlet port **27'** is not fitted with inlet duct, such as duct **34** of the first device **20**. While first device **20** collects tissue bits, device **80** collects the body fluids and thus serves as a liquid trap. If desired, an inlet duct with a tissue trap may also be provided at inlet port **27'** so as to collect residual tissue bits which escape trap **36** of device **20**. Such an additional trap within device **80** may have a finer mesh size than that of trap **36**. The structure and construction of such an additional trapping arrangement may be the same or different to that of trap **36** of device **20**, and although not illustrated, it is no doubt clearly understood to the artisan. Outlet port **28'** of device **80** is fitted with biological filter **84**, and a one-way valve **85**, e.g. a flood valve, both known *per se*.

Reservoir **50'** of second device **80**, typically contains a treatment material different than that contained in reservoir **50** of the first device **20**: that contained in reservoir **50'** is typically a preservation medium for preserving cellular, material contained in the liquid trapped in device **80**.

Reference is now being made to Figs. **3** and **4**, showing the system of Fig. **2** in two operational states. In the state shown in Fig. **3**, vacuum is applied at tube **83**, and, consequently, tissue bits and fluid collected by a probe (not shown) fitted at the end of inlet tube **82** are drawn through tube **83**. The liquid and the tissue bits then enter the container through duct **34** into tissue trap **36**, wherein tissue bits **90** are entrapped while the drawn liquid **92** passes through trap **36**. This liquid **92** is sucked through opening **42** of duct **40**, then through tube **81** towards port **27'**, into container **80**, where the collected liquid forms a pool **94**.

After the suction operation is completed, the vacuum may be turned off. This is the state shown in Fig. **4**. Preferably, tubes **81, 82** and **83** are then removed, and the port may then be fitted with caps **30** and **32** of the first device **20**, and the corresponding caps **30'** and **32'**, of container **80**. With such

caps in place, the container may be transported or handled as will be explained below.

Reservoir **50** contains a liquid treatment material **64**, which may, for example be formaldehyde, as already pointed out above. After the suction operation is complete, caps **66** and **66'** can be removed and then knobs **58** and **58'** may be actuated by clockwise turning, which causes advancement of spike **56** to rupture film **52** (see Fig. 1). Liquid treatment material **66** then flows into container **21** and fills the bottom up to level **100.** The amount of liquid **66** should preferably be sufficient so that level **100** will be such so as to flood all tissue bits.

Reservoir **50'** may contain treatment material in the form of a liquid or with particulate solid, e.g. a powder or lyophilisate (a particular solid, once dispensed, comes into contact with the liquid **94** collected in container **80**, and dissolves therein.)

For removal of collected tissue, lid **23** may be opened. Alternatively, as already pointed out above, plug **26** is opened and removed pulling with it duct **34** with the attached trap **36** (See Fig. 6 and the description below). Similarly, the corresponding plug **26'** in device **80** may be removed to open opening **24'** out of which samples of the treated liquid **94** may be withdrawn. The device **80** may also be provided with aspiration duct, e.g. a duct similar to duce **40** of device **20** to allow withdrawal of liquid from device **80** by aspiration.

In accordance with an embodiment of the invention, container **20** and container **80** may be combined into one unit, permanently or detachably fixed to one another.

Reference is now being made to Figs. 5 and 6 showing device **100** in accordance with another embodiment. The device **100** is similar to device **20** shown in Fig. 1 and accordingly like elements have beginning like numbers. The difference between device **100** to device **20** is in that rather than having a lid **23**, container **21'** has an integral top wall **102**. Furthermore, rather

than having a single vacuum port **28**, the device is fitted with an auxiliary vacuum port **104**, provided with a lid **106**, which may be fitted with a biological filter and a one-way valve, similar to components **84** and **85**, respectively of device **80** shown in Fig. 2. This device can serve as a standard design in a two-device system, one for collecting of tissue bits and the other for collecting of liquids, such as the system shown in Fig. 2. In such a two-device system, port **28** will be utilized in the first device, with port **104** being sealed, while in the second device, port **104** will be used with port **28** being sealed (port **28** may serve for liquid withdrawal as explained above).

Fig. 6 illustrates the step of removal of the collected tissue bits. Plug **26** is opened and detached from opening **24**, and withdrawn together with duct **34** which is integral therewith. Prior to complete withdrawal, hook **35** is hung on to cylindrical wall **25**, to allow drainage of remaining liquid from trap **36**, and after complete drainage, the trap may be removed for staging of the tissue bits.

CLAIMS:

1. A suction drainage device comprising a tissue collecting container with an inlet port for connecting to an inlet tube line leading from the source to be drained, and a vacuum port for connecting to a vacuum source; the device being characterized by:

an inlet duct which extends within the container from the inlet port terminating at an end fitted with a tissue trap for retaining tissue bits and allowing fluid passage therethrough;

a vacuum duct which extends within the container from the bottom wall of the container to the vacuum port; and

a sealed reservoir integral within the container and containing a liquid tissue- treatment material and provided with an external actuator for dispensing of the liquid tissue treatment material into the container so as to flood the tissue bits with said liquid.

2. A suction drainage device according to Claim 1, comprising two vacuum ports, one having a vacuum duct extending therefrom to the bottom wall of the container and the other being without such a vacuum duct.

3. A suction drainage device according to Claim 1, wherein the inlet port is defined within a removable plug sealing an opening in a top wall of the container.

4. A device according to Claim 3, wherein the inlet duct comprises a hook for retaining the duct in a hanging manner in said opening for draining the trap dependent therefrom.

5. A device according to Claim 1, formed as a disposable device.

6. A device according to any one of Claims 1-5, wherein the trap is a mesh made of flexible or pliable material.

7. A device according to Claim 6, wherein the trap is a nylon mesh.

8. A device according to any one of Claims 1-7, wherein the vacuum duct has an opening adjacent a bottom end of the container to allow withdrawal of substantially all liquid drained through the tissue trap.

9. A device according to any one of Claims 1-8, wherein the reservoir has a tearable or pierceable wall portion, which is ruptured upon user actuation.

10. A device according to any one of Claims 1-9, wherein the liquid treatment material contained within the reservoir is at an amount sufficient to flood all tissue bits once dispensed into the container.

11. A device according to Claim 10, wherein the tissue trap is at the container's bottom.

12. A device according to any one of Claims 1-11, wherein the liquid treatment material is a tissue fixative.

13. A device according to any one of Claim 1-12, connected in series to a liquid trap for collecting liquid drawn out of the container's vacuum port.

14. A suction drainage system comprising a device according to any one of Claims 1-9, and a liquid trap connected in a series therewith.

15. A system according to Claim 14, wherein the liquid trap is a second container with a reservoir containing a treatment material, which reservoir can be opened by user actuating to dispense the treatment material into the container.

16. A system according to Claim 15, wherein the reservoir of a first, tissue collection container, contains a fixative, and the reservoir of the second container contains a treatment material for preserving cellular material in the collected liquid.

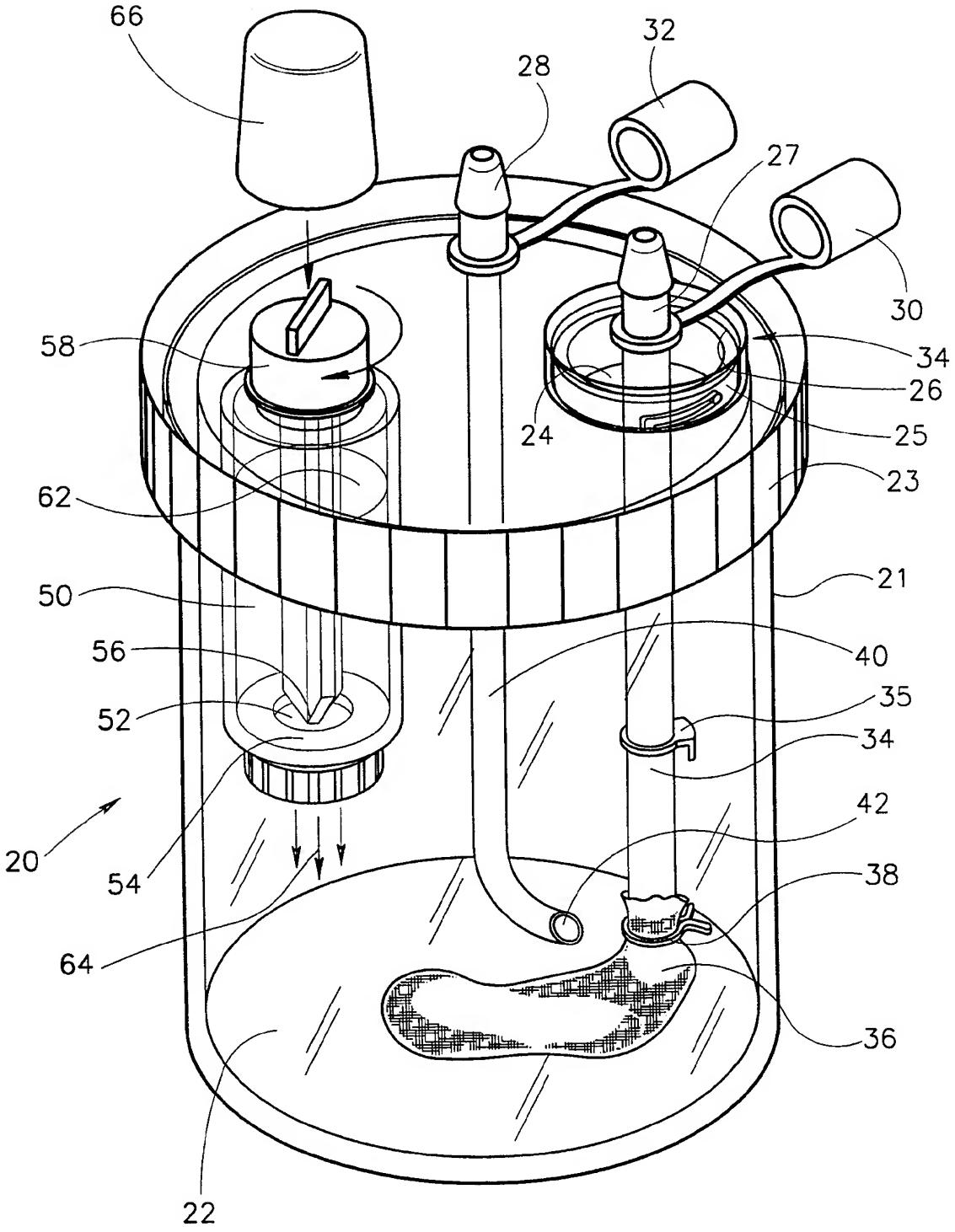
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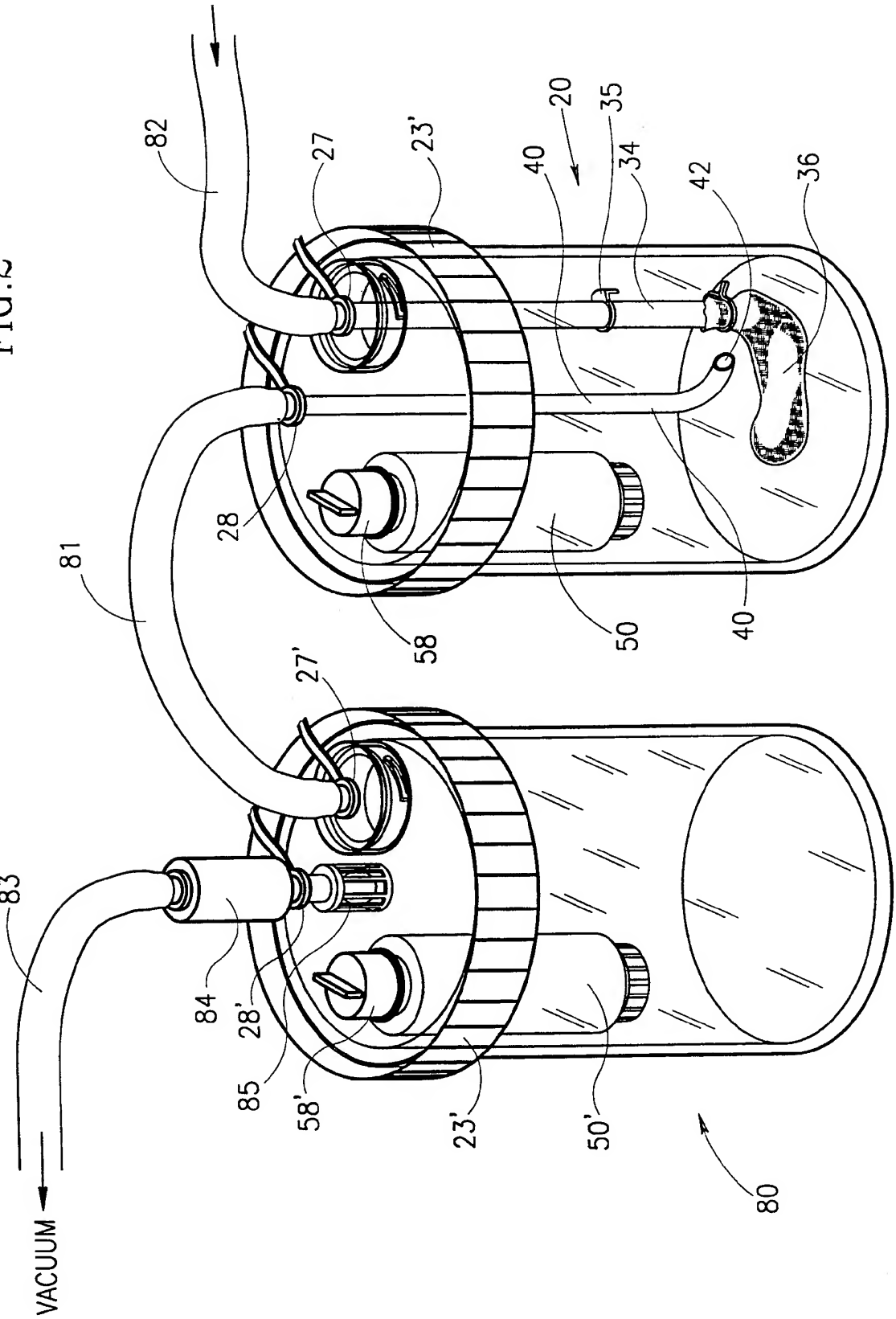
FIG.1

FIG.2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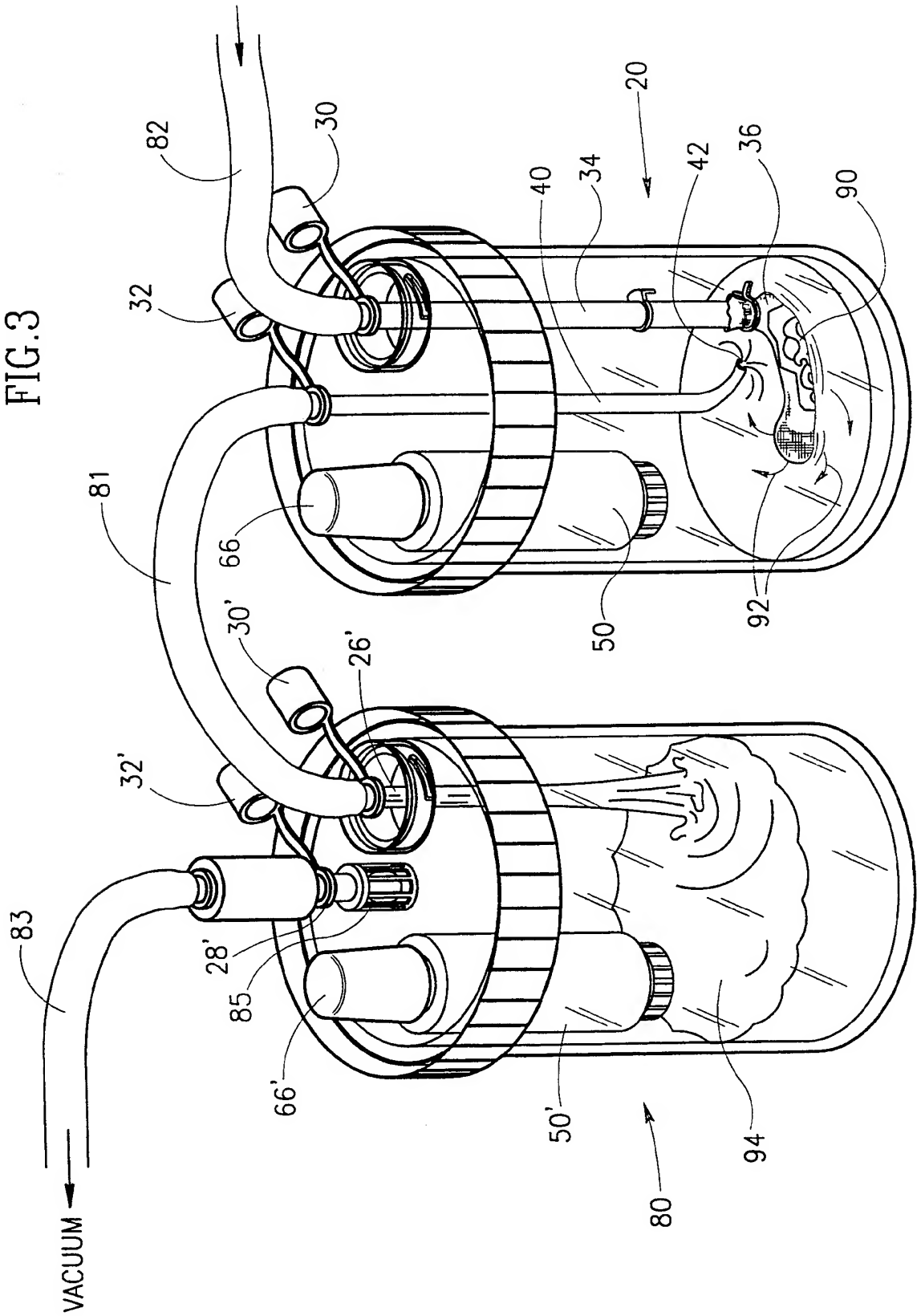
VACUUM

FIG.3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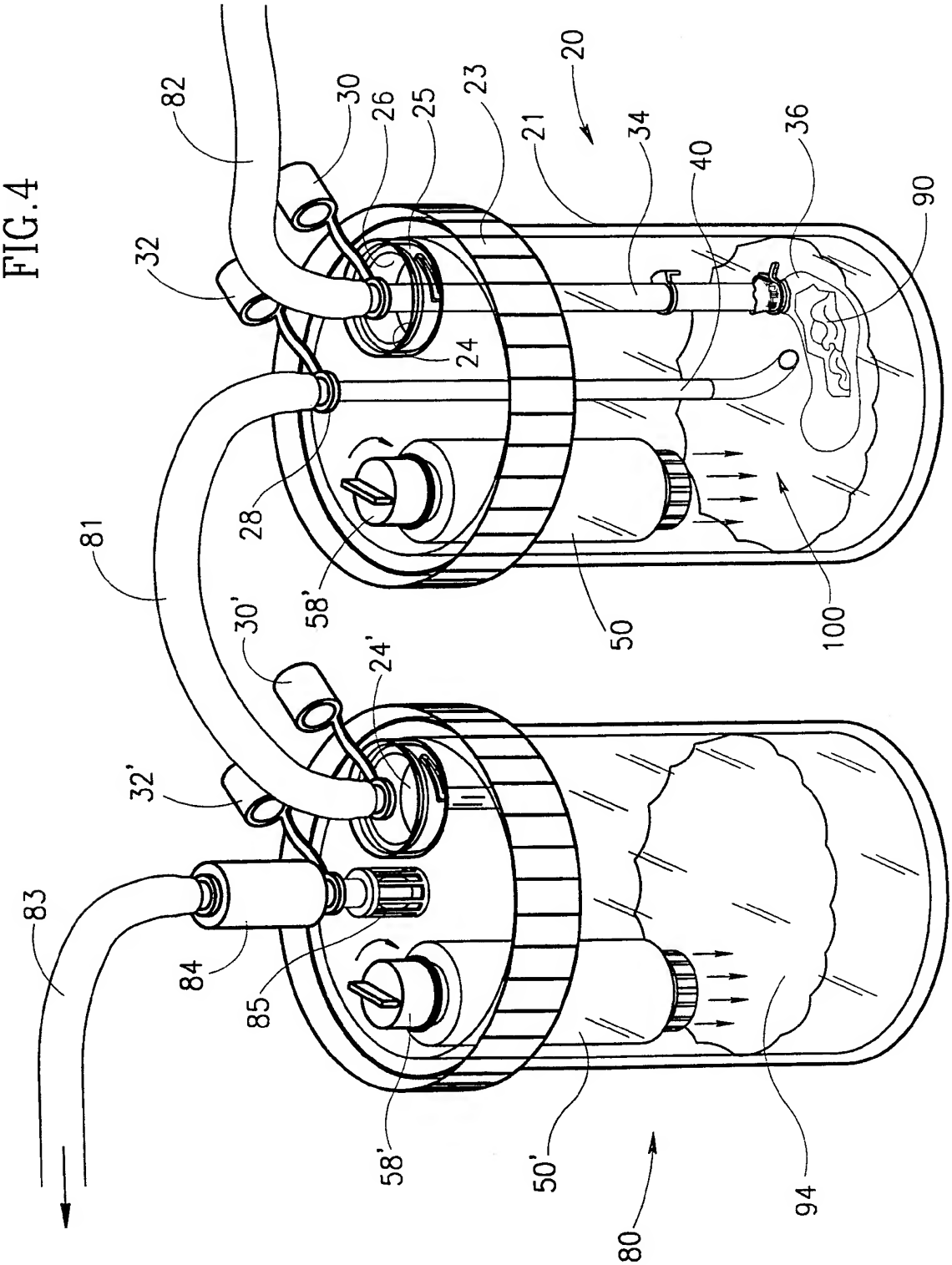
VACUUM

FIG.4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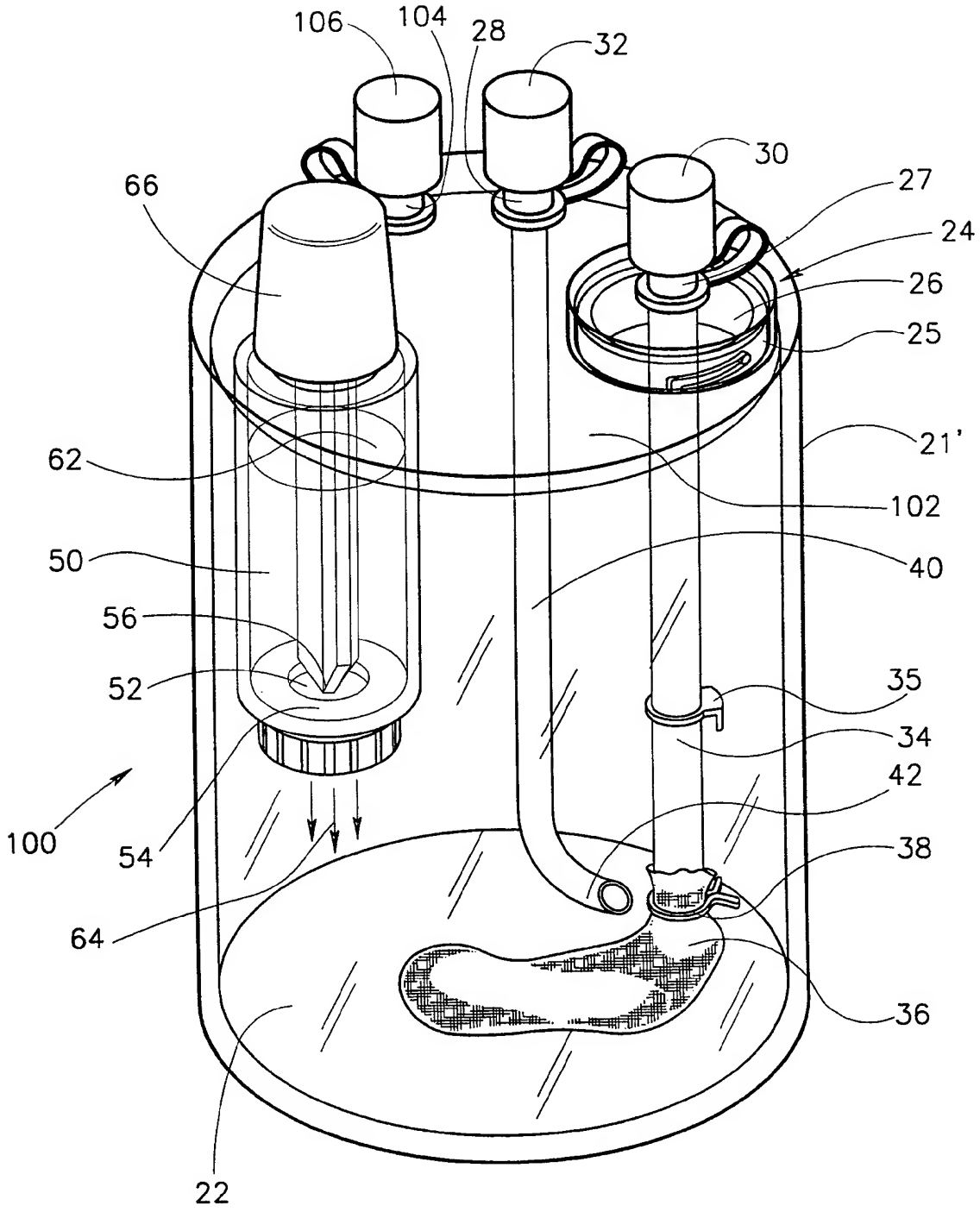
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FIG.5

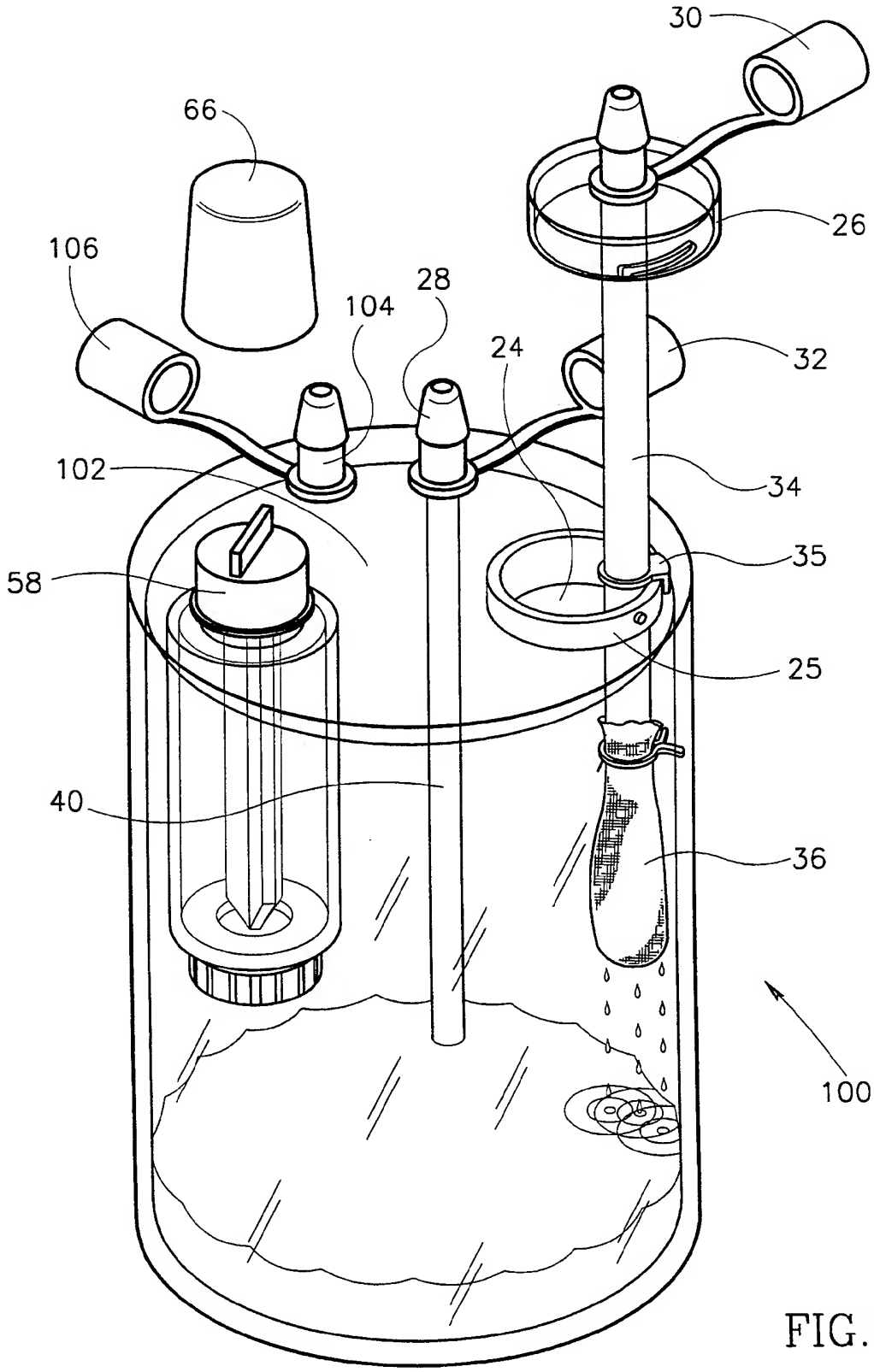

FIG.6

INTERNATIONAL SEARCH REPORT

Int. ional Application No
PCT/IL 98/00619

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M1/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 001 718 A (CHINOIN) 2 May 1979 see page 2, line 28 - page 3, line 14 see page 9, line 22 - page 12, line 9 see figures 1,2 ---	1,3,5,8, 10-12
Y	US 4 643 197 A (GREENE ET AL.) 17 February 1987 see column 2, line 29 - column 4, line 57 see figures 1-7 ---	1,8-10, 13,14
Y	EP 0 390 094 A (ABBOTT LABORATORIES) 3 October 1990 see claim 1 see figures 1,3 --- -/--	1,8-10, 13,14

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
23 March 1999	31/03/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Schönleben, J

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INTERNATIONAL SEARCH REPORT

Int. ional Application No
PCT/IL 98/00619

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 575 293 A (MILLER ET AL.) 19 November 1996 see column 3, line 63 - column 4, line 52 see figures 2,4	1,3,6,7
A,P	GB 2 323 288 A (VACSAX LIMITED) 23 September 1998 see page 3, line 12 - page 6, line 20 see figures 1,2	1,8-10, 13,14

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INTERNATIONAL SEARCH REPORT

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